



Everything You Need to Know About MegaSporeBiotic™

MegaSporeBiotic™ is the first 100% spore-based, broad-spectrum probiotic clinically shown to improve leaky gut in just 30 days. Spore-based probiotics are much more effective than conventional probiotics on the market because they are designed to survive through the harsh gastric system, colonize, and increase microbial diversity in the gut. Because these spores are so multi-functional, they can support a variety of functions in the body. This unique all-spore formula effectively reconditions the gut by increasing microbial diversity and encouraging the growth of key health-promoting, commensal gut bacteria. MegaSporeBiotic™ boasts a 5-year shelf-life, does not require refrigeration, and maintains efficacy during antibiotic therapy.

Ingredients:

MegaSporeBiotic™ contains 5 strains of Bacillus including:

- Bacillus subtilis HU58
- Bacillus clausii SC-109
- Bacillus coagulans SC-208
- Bacillus indicus HU36
- Bacillus licheniformis SL-307

All 5 of these strains were originally isolated from a healthy human gut at Royal Holloway University of London by Simon Cutting. The "HU" in the strain number represents Holloway University, and the "SC" represents Simon Cutting. The original bacterial strains are kept in a bacteria bank at Royal Holloway University of London. When it is time for production, the bacteria are checked again for proper characterization and DNA-verified to be the correct strains. Those strains are shipped individually to a pharmaceutical-grade fermentation facility, where they are grown to the quantities required and then shocked back into their spore form for 100% spore delivery. MegaSporeBiotic™ also contains cellulose from acacia wood fiber that acts as a prebiotic for gut bacteria. The 5 spores and cellulose are encapsulated in a vegetarian capsule made of cellulose from pine trees and water.

The strains in MegaSporeBiotic™ can range in color from white or yellow in appearance to black or gray in color. When mixed together, capsules can contain black flecks or a yellow hue. The blended powder is completely natural and unbleached, so color variation is quite common from batch to batch. This product is routinely tested a minimum of 4 times before it reaches the end consumer. MegaSporeBiotic™ is a pure fermentation extract and with nature there is no color uniformity.



Why Bacillus?

Bacillus spores are naturally designed to survive digestion. The reason for their inherent survivability comes from their bi-phasic life cycle. This means that the Bacillus spores can transition interchangeably from their dormant form to their active form, depending on the environment. In its dormant spore form, Bacillus will surround itself with an endospore, which is a tough, natural outer shell that protects it from light, heat, pressure, acid, lack of oxygen, and other environmental factors.¹ This key feature is what allows MegaSporeBiotic™ to survive easily through digestion without the need for enteric-coated capsules or refrigeration. Once it reaches the intestines, MegaSporeBiotic™ can increase microbial diversity by changing the pH, crowding out unwanted pathogens, and increasing the production of short-chain fatty acids. Due to its inherent survivability and lasting health benefits, MegaSporeBiotic™ has become a revolutionary tool in achieving Total Gut Restoration.

Function

According to research by the National Institute of Health, the definition of a probiotic is as follows: 1. The organism must be a normally occurring organism in the digestive tract. 2. In order to consistently trigger a healthy boost in immune function the organism must be supplemented in concentrations higher than what normally occurs in the digestive tract. 3. The organism must be able to survive in the digestive tract as well as in the environment.

Interestingly enough there are almost no probiotics in the marketplace that meet all three of these criteria besides MegaSporeBiotic™. The spores used in MegaSporeBiotic™ have been shown to effectively modulate the immune system, reduce intestinal inflammation, and even reduce biomarkers of leaky gut.²⁻⁴

MegaSporeBiotic™ contains 5 pharmaceutical-grade strains that each have unique function and thus contribute to the overall effectiveness of the product.

Bacillus indicus HU36 The first carotenoid-rich probiotic strain offered to the dietary supplement market. *B. indicus* HU36 produces high levels of powerful carotenoids (antioxidants) at the site of absorption.^{5,6} Supplemental carotenoids do not survive the gastric system well; however, HU36 has demonstrated the ability to survive the stomach acid and produce the carotenoids at their site of absorption in the gut. This makes the carotenoids produced by HU36 the most bioavailable supplementary carotenoids in the marketplace.

Bacillus clausii SC-109 *Bacillus clausii* is among the most commonly used probiotic strains for bacteriotherapy in a variety of applications. It has been used in the pharmaceutical industry for over 50 years with high efficacy and excellent



tolerability. One of the first commercial probiotic products ever launched into the market was the prescription product Enterogermina® by Sanofi-Aventis in Italy in 1958. Since the onset of clinical use of *B. clausii* in 1958, there have been a number of clinical studies demonstrating its efficacy and safety. *Bacillus clausii* is recommended for immune modulation and use during antibiotic treatment due to its ability to mitigate damage from a variety of common antibiotics.⁷

MegaSporeBiotic™ has the unique function of remaining effective when used in conjunction with antibiotic therapy to keep the organisms balanced in the gut. As a potent immune modulator, *B. clausii* has been shown to significantly reduce allergic symptoms in children with recurrent respiratory infections.^{8,9} In these studies, a Th1 (T-helper 1) bias was observed showing that ingestion of *B. clausii* could enhance the cellular immunity in allergic children who normally carry a Th2 bias.

Bacillus subtilis HU58 *Bacillus subtilis* has been extensively studied on a genetic and functional level. There are several probiotic products in the pharmaceutical and agricultural markets that utilize this powerful probiotic. One very interesting function of *Bacillus subtilis* is its ability to produce nearly 12 strong antibiotics that are potent fighters of opportunistic and harmful bacteria.¹⁰ *Bacillus subtilis* HU58 offers MegaSporeBiotic™ the ability to prevent harmful bacteria growth in a variety of conditions. In addition, *B. subtilis* HU58 produces a very beneficial proteolytic enzyme called nattokinase. Nattokinase is secreted from active cells of *Bacillus subtilis* and has been shown to reduce blood pressure, cholesterol, and excessive clotting through fibrinolysis.¹¹ Along with nattokinase, *Bacillus subtilis* HU58 also produces a number of other nutrients that have systemic health benefits such as the full spectrum of B vitamins and vitamin K2 (MK-7).¹² *Bacillus subtilis* HU58 offers MegaSporeBiotic™ the important function of fighting off pathogenic bacteria and producing key nutrients directly in the gut. In addition, *Bacillus subtilis* HU58 is an extremely potent immune modulator.³ It has the function of germinating in the small intestines to some degree and this offers the effect of broad-spectrum immune stimulation.¹³ *Bacillus subtilis* HU58 has been shown to ferment dietary starches into shortchain fatty acids (SCFA) such as butyrate, acetate and propionate which have effects in variety of health conditions.¹⁴ Butyrate is the major energy source for colonocytes and has been studied for its role in nourishing the colonic mucosa. Studies indicate that butyrate may play a significant role in the prevention of colon cancer and amelioration of intestinal inflammation.¹⁵ Therefore, a greater increase in SCFA production, specifically butyrate, in the distal colon may have a protective effect on the digestive tract.

Bacillus licheniformis SL-307 *Bacillus licheniformis* is a ubiquitous organism that has been consumed by and exposed to humans for millions of years. A probiotic often found with *Bacillus subtilis* and other *Bacillus* species, *B. licheniformis* produces a number of important compounds, including the common antibiotic bacitracin.¹⁶



This is a thermostable antibiotic that is also resistant to enzymatic degradation, which makes it very effective in the gut. *B. licheniformis* produces this antibiotic in the presence of pathogens, and it is very effective against pathogens like *Vibrio* spp. In addition to the antibiotics, it produces a very stable protease enzyme that assist in the digestion and absorption of proteins.¹⁷ Lastly, *B. licheniformis* also produces the full spectrum of B vitamins in the gut, including folate and biotin, and acts as an important nutrient factory in the digestive system.¹²

Bacillus coagulans SC-208 *Bacillus coagulans* has a long history of use for its health benefits in humans. *Bacillus coagulans* is very unique in that it possesses characteristics of both *Bacillus* and *Lactobacillus* species. Unlike other lactic acid-producing bacteria, *B. coagulans* produces L-lactate which has been shown to have a more profound effect on immune stimulation and gut defense than D-lactate produced by conventional probiotics.^{18,19} Lactic acid-producing bacteria have been extensively investigated for their role in the gut microbiome, and they appear to play an important role in maintaining a healthy digestive tract. *B. coagulans* is a strong colonizer in the gut and also plays a key role in the digestion and absorption of nutrients, like lactose and dietary fats.²⁰ *B. coagulans* possesses the potent ability to soothe intestinal inflammation through the production of butyrate, aid in digestion, and prevent the growth of harmful bacteria.²¹

Research

While many companies rely on single strain research to support their multi-strain probiotics, it's important to look for human clinical trials performed with finished products. MegaSporeBiotic™ was used as the treatment in a randomized, double-blind, and placebo-controlled trial to evaluate the ability of the probiotic to reduce or prevent metabolic endotoxemia, or leaky gut.⁴ In addition to assessing changes in dietary endotoxemia, the researchers also measured transient changes in cardiovascular disease (CVD) risk factors, other novel disease risk biomarkers, and the immune system itself, following a high-fat challenge meal.

Metabolic endotoxemia is an innate immune response that results in sub-clinical, low-grade inflammation due to elevated circulating endotoxins. The primary endotoxin of concern is lipopolysaccharide (LPS). LPS is a major component of the outer cell membrane of gram negative bacteria residing in the gut. In fact, the majority of the microbes in the digestive tract are gram-negative bacteria, including *Clostridium* spp., *Enterococcus* spp., *Escherichia* spp., and *Bacteroides* spp. Trillions of commensal bacteria in the gastrointestinal tract contain LPS, and when these bacteria die, they release LPS into the intestines. This process happens quite frequently, as many bacteria die off during a meal, but LPS remains harmless when it is kept inside the intestines. It is not until LPS reaches the intestinal lining and enters circulation that it begins to trigger low-grade inflammation.



Once inside the circulatory system, LPS can trigger innate immune activation and subsequent inflammation anywhere in the body. LPS can delay gastric emptying, slow bowel motility, disrupt ghrelin function, inhibit testosterone production, reduce serotonin, and so much more. Metabolic endotoxemia could very well be the primary driver of most chronic illnesses plaguing the western world.

In the Leaky Gut study involving MegaSporeBiotic™, healthy volunteers were screened for an endotoxic response to a high-fat challenge meal. If they showed an endotoxic response, they were enrolled into the study and randomized into either the placebo group or treatment group. They consumed the placebo treatment or MegaSporeBiotic™ for 30 days, with no other interventions or lifestyle changes. After the 30 days, they reported back to the lab for their "post-treatment" response and received a second challenge meal. All the same blood work was run to assess their levels of endotoxemia. The data showed a clear shift to a protective microbiome after just 30 days of supplementation with the Bacillus spores. The post-test challenge in the treatment group showed a drastic reduction in endotoxemia. Interestingly, the placebo group progressively worsened. These probiotic spores are likely the most promising therapy for leaky gut, as no other probiotics or compounds have demonstrated this effect. Collectively, the findings of this study demonstrate a significant blunting of LPS, triglycerides, and systemic inflammatory markers IL-6, IL-8, MCP-1, IL-1 β , and IL-12 following a 30-day period of supplementation with MegaSporeBiotic™. This study is the first to demonstrate that a short-term probiotic intervention can alter leaky gut in human subjects.

MegaSporeBiotic™ is currently involved in over 10 active clinical trials investigating its therapeutic effects on acne, triglycerides, liver protection, periodontal disease, cancer immunotherapy, weight loss, hepatic encephalopathy, and more with exciting results that are presently awaiting publication.

Indications

Leaky Gut, Autoimmune Disorders, Seasonal Allergies, Food Allergies Food Sensitivities, Irritable Bowel Syndrome, Crohn's Disease, Ulcerative Colitis, Diverticulitis, Celiac Disease, Candida Overgrowth, Parasitic Infection, Clostridium difficile Infection, Helicobacter pylori Infection, Small Intestinal Bacterial Overgrowth (SIBO), Small Intestinal Fungal Overgrowth (SIFO), Acne, Psoriasis, Eczema, Diabetes, Obesity, Infertility, Polycystic Ovarian Syndrome, Metabolic Syndrome, Cardiovascular Disease, Kidney Disease, Liver Disease, Alzheimer's Disease, Parkinson's Disease, Hepatic Encephalopathy, Recent Antibiotic Use.



Advantages

Most probiotics on the market contain some combination of Lactobacillus and/or Bifidobacterium. However, these products are often single strain-single effect probiotics that have a difficult time surviving the harsh environment of the gastric system. The strains found in MegaSporeBiotic™ are gut commensal organisms that are uniquely built to survive harsh environments like the digestive system, which is what allows them to effectively colonize in the gut.

MegaSporeBiotic™ differs from other probiotics on the market in a number of ways:

1. Survivability – MegaSporeBiotic™ contains 5 strains of Bacillus that have been shocked back into their resilient spore form. In this form, the bacteria are impervious to heat, light, acid, pressure, radiation, and lack of oxygen.¹ This unique feature allows MegaSporeBiotic™ to naturally survive the harsh gastric system.

2. Leaky Gut Repair – MegaSporeBiotic™ has been clinically shown to heal leaky gut in a matter of 30 days without any additional interventions, making MegaSporeBiotic™ one of the most effective leaky gut solutions on the market today.⁴

3. Carotenoid Production – Carotenoids are the beneficial antioxidants found in colored fruits and vegetables. However, carotenoids from dietary supplements are poorly absorbed, and most people do not eat as many colored fruits and vegetables as they should. For these reasons, supplementation with a carotenoid-rich probiotic is highly important. These beneficial bacteria produce high levels of carotenoids right at the site of absorption, thus allowing for optimum uptake into the body.^{5,6}

4. Increased Microbial Diversity – The bacterial strains in MegaSporeBiotic™ have been shown to significantly increase microbial diversity in the gut in a SHIME study awaiting publication.

5. Competitive Exclusion – The spores found in MegaSporeBiotic™ have the ability to detect harmful and opportunistic pathogens through a method known as quorum sensing. This allows the spores to identify and crowd out any unwanted pathogens in the gut.¹

6. Immune Support – Studies show that Bacillus subtilis promotes the development of GALT, which is critical to the formation of a properly functioning and robust immune system.²² MegaSporeBiotic™ also supports the immune system by stimulating Peyer's patches, as well as Toll-like receptors, in order to improve pattern recognition, increase circulating T and B lymphocytes, and upregulate regulatory T cells. The end result is a healthier gut lining and a stronger immune



system that is better equipped to handle unfavorable lifestyle and environmental factors that can lead to conditions like asthma, allergies, autoimmunity, and infections.

7. Metabolic Reconditioning – The latest research has shown that the type of bacteria in the gut can dictate food cravings and even calorie extraction from ingested foods.²³ These effects are realized by turning on crucial genes in the digestive tract that control our metabolic fate. MegaSporeBiotic™, in conjunction with a higher protein, low sugar, and fiber-rich diet, can reprogram the body through the modification of key genetic activation to favor fat burn, reduce fat accumulation, and increase energy metabolism, satiety, and insulin sensitivity.

Suggested Use

While there is no known upper limit for MegaSporeBiotic™, the ideal dose is 2 capsules per day in order to stimulate the Peyer's patches and encourage immune modulation. MegaSporeBiotic™ is most effective when taken with a meal, but it will not cause an upset stomach if taken without food. The amino acids and carbohydrates in food can help the spores move from their dormant (spore state) to their active (vegetative state) form in the GI tract, so it is ideal to take MegaSporeBiotic™ with a meal. Because the encapsulated probiotics are in their spore form, they do not need the capsule in order to survive digestion. For this reason, the capsules can be pulled apart, and the powder can be mixed into nearly any food or drink for convenience. MegaSporeBiotic™ is temperature stable, so it can even be mixed into hot tea, coffee, or soup. There is no real taste impact of the powder, which should make it easier to administer to children.

Titration Schedule

MegaSporeBiotic™ is a very potent probiotic, and for this reason, we recommend starting very slowly with ½ or even ¼ capsule and slowly increasing to the target dose of 2 capsules per day for anyone over the age of 3 years old and 1 capsule per day for infants and toddlers. If the child appears to be sick or getting sick, you can increase to 2 capsules per day. The target dose of MegaSporeBiotic™ is not determined by weight or age but by the development of the gut microbiome, which is fully formed around 2.5 years of age.²⁴

Start with ¼ or ½ capsule with food and slowly increase to 2 capsules per day using the following the protocol:

Week 1: Take ½ capsule every other day
Week 2: Take ½ capsule daily
Week 3: Take 1 capsule daily
Week 4+: Take 2 capsules daily

**Note:**

- MegaSporeBiotic™ is a very potent probiotic that can crowd out pathogenic bacteria and may therefore result in die-off symptoms. These symptoms include,
- but are not limited to: bloating, abdominal cramping, gas, changes in stools (drier, harder stools or loose, watery stools), temporarily worsening seasonal allergies, changes in energy levels, and more.
- If ½ capsule every other day is too strong, try starting with ¼ capsule or just a pinch of the probiotic powder in some cases. Highly sensitive individuals may want to take with Mega IgG2000 from the start.
- MegaSporeBiotic™ is safe and highly recommended during pregnancy and nursing. If the pregnant or nursing mother has severe inflammatory conditions or yeast issues, they should titrate up slowly to avoid a strong detox reaction.

MegaSporeBiotic™ is extremely effective at reconditioning the gut microbiome, and as a result, it is very common to feel the effects of this transition period. Please note that this change is positive and a sign that MegaSporeBiotic™ is working. Loose, watery stools are most common when starting MegaSporeBiotic™, as the spores begin to crowd out pathogenic bacteria. As these pathogens die, they release a high concentration of toxins into the gut, which the body compensates for by increasing water retention in the intestines in order to flush these toxins out of the system.

This transition period should only last 3-4 days. If these mild die-off symptoms last longer than 5 days or are too intense, then your dose is likely too high and you are experiencing a strong die-off reaction. For the sake of comfort, you can decrease your dosage and continue at a slower pace, you can add Mega IgG2000 to help soak up the additional toxins, or you can power through the transition phase. Your titration depends entirely on you, your health goals, your medical history, your lifestyle, and your own preferences. As with any health recommendation, there is not one size that will fit every need. Consult your healthcare practitioner for an individualized treatment plan.

Synergy

At about 21 days, the Bacillus strains found in MegaSporeBiotic™ will begin to reach a steady state concentration in the gut. This is when it's important to consume a diet low in refined sugars and higher in fibers to facilitate the growth of the one's own beneficial bacteria. MegaSporeBiotic™ can be used alongside any other products from Microbiome Labs. Adjunct probiotics like RestorFlora and HU58 can be taken in conjunction with MegaSporeBiotic™ in order to increase the efficacy and crowding out of pathogens. MegaSporeBiotic™ is safe to take with digestive



enzymes, betaine HCl, antibiotics, and even activated charcoal. MegaSporeBiotic™ is most effective when taken with the other products in the Total Gut Restoration system, MegaPreBiotic (to REINFORCE the beneficial changes from MegaSporeBiotic™) and MegaMucosa (to REBUILD the protective mucosal barrier in the gut).

Duration

Nature has designed these spores to be a daily, foundational food. They are transient microorganisms, which means that they don't stay in the gut forever. Instead, they enter the intestines, perform a function, stay for about 21-28 days, and then leave. This is important as this helps keep their abundance in the gut microbiome relatively low, making each dose of MegaSporeBiotic™ very effective. While most people notice the benefits of MegaSporeBiotic™ within the first 14-28 days, this spore-based probiotic will be most effective if taken at the full suggested dose of 2 capsules per day for 2-3 months or until unwanted symptoms subside. Reconditioning the gut microbiome after a round of antibiotics or following a severe gut infection may take 4-6 months. Unlike most probiotics on the market, MegaSporeBiotic™ will not lose efficacy after a few months, so there is no need to rotate it with other probiotics – which is a marketing ploy and has no basis in science.

The recommended time to stay on the full dose of MegaSporeBiotic™ will vary by individual, but there is no known upper limit or contraindications to taking MegaSporeBiotic™ at the full dose indefinitely. Due to the transient nature of Bacillus probiotics, long-term use is suggested but daily use may not be necessary for maintenance. Once the problematic symptoms have subsided, there is always an option to drop down to a maintenance dose of MegaSporeBiotic™. When working towards a maintenance dose, it's important to continue taking 2 capsules together in one day. However, the frequency can be slowly decreased from 2 capsules daily to 2 capsules every other day, then 2 capsules every 2 days, and ultimately 2 capsules on the weekends.

While this maintenance dose is available, most people find that daily use provides the best results, as many people damage their gut microbiomes on a daily basis.

Contraindications

There are no real contraindications for the use of MegaSporeBiotic™. However, it's important to understand that this probiotic is a powerful immune modulator. New evidence suggests that autoimmune conditions are the result of an immature and untrained immune system, rather than an overactive immune system, but anyone taking immunosuppressant medications should speak with their physician before taking MegaSporeBiotic™ in order to weigh the benefits.



Background

Found naturally in the environment for millions of years, *Bacillus* spores have developed a symbiotic relationship with their human host. Our ancestors derived probiotic benefits from inadvertently consuming *Bacillus* spores on a regular basis. In fact, the oldest bacterial spore ever documented was 250 million years old and found inside salt crystals in Carlsbad, New Mexico. Though it sounds like science fiction, scientists were able to isolate and grow the 250million-year-old spores!

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